

Remarks

Claims 1, 5 and 18 are amended in this application. Claim 19-20 are added as dependent claims of claim 1. Claims 2, 14 and 15 are canceled. No issue of new matter arises.

Response to 35 U.S.C. § 112 rejection

The Examiner rejected claims 1 and 3-18 under 35 U.S.C. § 112, *second paragraph*, alleging that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Applicants have amended claims 1, 5 and 18 to clarify the relationship between the reporter gene and target molecule, and to state that “said target molecule effects the activity of said reporter genes”. The amendment of above claims is based on the disclosure on page 11, lines 11-15 of this application. No new matter is added by this amendment.

Applicants cancelled claims 14-15 without prejudice. Applicants reserve the right of filing divisional application(s). After this amendment, the rejection has been overcome and Applicants respectively request reconsideration and withdrawal of this rejection.

Response to 35 U.S.C. § 102 rejection

The Examiner rejected claims 1-5, 12-14 and 16-17 under 35 U.S.C. § 102(b) as the claims are allegedly anticipated by Pausch (TIBTECH 15, 487-494, 1997). According to the Examiner, Pausch teaches a method of identifying an agent that modulates the activity of a target molecule by contacting a cell and modulating a target molecule, wherein an agent, somostatin, modulates a target molecule, Sst2, which induces a FUS1-HIS3 reporter in a *S. cerevisiae* cell.

The Examiner rejected claims 1, 5, 10-11 and 18 under 35 U.S.C. § 102(b) as the claims are allegedly anticipated by Crossin et al. (PNAS 94, 2687-2692, 1997). The Examiner stated that Crossin et al teaches a method of identifying an agent that modulates the activity of a target molecule by contacting a cell and modulating a target molecule, wherein an agonist, N-CAM, modulates a target molecule, GRE, which induces a luciferase reporter.

The Examiner rejected claims 1-7, 9-11 and 13-14 under 35 U.S.C. § 102(b) as the claims are allegedly anticipated by Keating et al. (Oncogene 20, 4281-4290, 2001). The Examiner stated that Keating et al teaches a method of identifying an agent that modulates the activity of a target molecule by contacting a cell and modulating a target molecule, wherein an agent, EGF, modulates a target molecule, ATM, which induces a luciferase reporter.

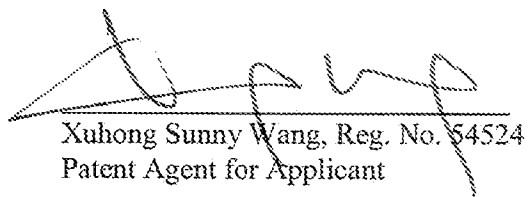
In order to expedite the prosecution of this application, the Applicants respectfully redirect the present embodiment of the claims to a double reporter gene assay as described on page 11 (lines 11-15) page 12 (lines 9-12) and pages 18-19 (Example 1-3) of this application as a preferred embodiment. In the disclosed assay of this application, one reporter is a growth marker gene, and the other reporter gene is an enzyme or a fluorescent protein. The advantage of this assay system is that only this combination of growth, a logarithmic event, and linearly induced expression of a measurable enzyme or fluorescent protein leads to an amplification of the signal, i. e. a large measurement window above the baseline (see cited paragraphs, page 11, lines 11-15; page 12, lines 9-12; pages 18-19, Example 1 and 3, Fig 1c, and Fig 3). On page 18, Example 2 describes the results of a comparison experiment of a single reporter gene assay with only a small measurement window, if any, and a double reporter gene assay with a large measurement window. This double reporter gene assay and its feature neither is disclosed nor suggested in any of the three references cited by the Examiner as being anticipating over the claimed invention.

Each reference cited by the Examiner discloses only a single reporter gene assay. Pausch (1997) discloses somatostatin-induced growth (see TIBTECH 15, 487-494, Fig 1b). Keating et al (2001) discloses EGF-induced luciferase activity (see Oncogene 20, 4281-4290, page 4288). The same is true for Crossing et al. (1997) as disclosed in Fig 4 on page 2680 (see PNAS 94, 2687-2692). Each reference cited by the Examiner fails to teach every element of the claimed invention, i.e. a double reporter gene assay system. Thus, the rejection has been overcome and withdrawal of the rejection is respectively requested.

The Applicants respectfully submit that the specification and claims, as amended, are in condition for allowance, and respectfully request early, favorable action on the application.

Should the Examiner believe that an interview would advance the prosecution of this application, the Applicants invite the Examiner to contact the undersigned at 908.231.3648.

Respectfully submitted,



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